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QUALITY PROGRAM FOR SUPPLIERS (QPS)

QUESTIONNAIRE

APPLICANT'S

QUALITY PROGRAM

VS

QPS STANDARD REQUIREMENTS

The American Society of Mechanical Engineers
Conformity Assessment Department
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INTRODUCTION

This Guide is intended to be used by Applicants of the ASME QPS Program, to determine the degree of conformance of their Quality Program to the 17 essential requirements of the ASME Quality Program for Suppliers: General Industry (QPS) Standard. It is not intended to replace or interpret the requirements of the QPS Standard. This guide is provided as a tool to assist Applicants in identifying the strengths and weaknesses of their quality program when applying the requirements of the QPS Standard.

This Guide is based on the QPS Standard and is subject to revision based on changes made in the Standard.

It is recognized that the scope of work will vary from applicant to applicant therefore, only those activities to be performed under the scope of the applicant's Quality System Certificate are required to be addressed in the Quality Program. Therefore, there may be questions that are not applicable. The Applicant's Quality Program Manual need not follow the format of this Guide.

Suggestions for revisions or clarification to this Guide should be directed to the ASME Director of Accreditation and Certification.

HOW TO USE THIS GUIDE

The Applicant shall review each question, along with the QPS Standard requirements of the specific section referenced in this guide and determine if the QPS Standard essential requirement is adequately covered in its quality program.

	2-1.1 General	
1	(a)	Does organization establish, document, implement and maintain a Quality Program for all products and services provided in accordance with ASME QPS?
2		Does the Quality Manual or equivalent Quality Document meet the following requirements? - Policy declaration - Interaction & sequence of processes - Organizational chart
3		How are responsibilities, authorities and accountabilities defined, documented, assigned, and communicated in the organization?
4	(b)	How does the organization determine and maintain the necessary competence and credential(s) for the personnel performing the work that affects the PRODUCT quality?
5		Is there a procedure for managing internal or external communications?
6	(a)	Does the Quality Manual or equivalent Quality Document meet the following requirements? - Scope of the activity, including exclusions. - definition, approval of the measurable quality objectives with respect to the relevant functions - Protecting the integrity of ASME certificate
7		Does the Quality Manual or equivalent Quality Document contain references on the technical and control aspects that affect the quality of the product?
8	(b)	Does the Quality Manual or equivalent Quality Document include a documented process on managing the ASME QSP certificate and defining and communicating any significant changes?
	2-1.2 Quality Manual or equivalent Quality Document	
9	(c)	Is Quality Manual or equivalent Quality Document, suitable for use, and is it available where and when it is needed?
10		Is the Quality Manual or equivalent Quality Document adequately protected (i.e loss of confidentiality, misuse, loss of integrity)?
11		Does the Quality Manual or equivalent Quality Document meet all the requirements of the QSP standard?
12		Is the documentation supporting the quality manual or equivalent document complete to address compliance with the requirements of the technical work file and with this standard?
13	(d)	The format and structure of the Quality Manual or equivalent Quality Document are at the discretion of the organization and depend on the organization's size, culture, and complexity. Is the Quality Manual or equivalent Quality Document supported by procedures, Work instructions, Forms, (and /or) other documents?
14		Is a list of the documents contained in the Quality Manual or equivalent Quality Document kept up to date?
15	(e)	the organization shall plan, implement, and control the processes necessary to meet the requirements for the delivery of products and services. Have been criteria established for: - processes - acceptance of products and services - determine the resources needed to achieve compliance with the requirements. - implement process control. - determine and keep records as needed. - demonstrate compliance of products and services with their requirements
		2-1.3 Delegation of Duty
16		Is there a documented procedure for the delegation of roles and responsibilities for the activities /functions?
		2-1.4 Authorized Personnel
17	(a)	Is there a documented procedure for defining Authorization at each significant level or function?

18	(b)	The organization shall ensure that the arrangements planned to verify that the products and service requirements have been met. - Are there documented procedures for the definition of authorizations at the start of activities or any interruptions in the event of non-conformities found with respect to the requirements? - Have escalation procedures been defined?
19	(c)	Is there a documented procedure that demonstrates that employees are aware of their impact on product quality and the importance of their activity in achieving and maintaining and improving quality including risks related to non-compliance with customer requirements?
20		Is there a documented procedure for identifying training needs, including awareness to achieve the competence of personnel involved in activities that affect compliance with product or process requirements?
	2-2.1 General	
21	(a)	How are responsibilities, authorities and accountabilities defined, documented, assigned, and communicated in the organization? see 2.1.1 (a)
22		Has The organization establish, implement, documented, and maintain, and continually improve a quality management system, including the processes needed and their interactions, in accordance this standard?
23		Has been identified an individual of the organization's Management responsible for implementation and monitoring of quality program?
24	(b)	**See 2-1.4**
25	(c)	Has the authority, responsibility, delegation, and escalation of technical / quality personnel been defined regarding all activities that affect the quality of the products?
26		Does the health and safety management system address the safety of personnel without comprising the achievement of product quality requirements?
	2-2.2 Credentialed Personnel	
27		Is there a documented procedure for identifying the necessary credentials of the personnel involved in the quality system and the activities described in the technical job file?
28		Is employee credential/certification maintained where the quality outcome of process cannot be verified and it strongly dependent upon operator competence?
29		Are suitable methods used to verify training effectiveness?
30		Are suitable records maintained?
	2-2.3 Competency Requirements –Quality Manager	
31		Have the requirements of competence, experience in the function for the role of quality manager been defined as prescribed by the quality program?
32		Did the quality manager participate in the ASME QSP-1 standard course obtaining the credential?
33		Have criteria been defined for evaluating the experience and knowledge in the quality field of the quality manager?
	2-2.4 Competency Requirements –Quality Manager	
34		Have the requirements of competence, experience in the function for the role of technical manager been defined as prescribed by the quality program?
35		Have criteria been defined for evaluating the experience and knowledge of products, processes, and standards applicable to the design of the technical manager?
	2-2.5 Assessment of Resources by Executive Management	
36		Has the management of organization established, implemented, and maintained a documented procedure to identify the methods of monitoring, measuring, analyzing, and evaluating resources necessary to guarantee the performance and effectiveness of the quality system?

37		Has the periodicity for the analysis of the results obtained from monitoring and measurement of the adopted quality system been defined?
38		All the resources arising from the planned management review were systematically analyzed and implemented?
39		Have the training and education needs of the personnel been analyzed during the periodic management review in relation to the results of the monitoring of production processes?
	2-3.1 General	
40	(a)	Is there a documented procedure that defines responsibilities for the preparation, approval and issuance and changes of quality documents or that affect product quality?
41	(b)	How are documents of external origin verified to ensure that relevant versions are used and maintained?
42		How obsolete documents are identified and removed to ensure against unintended use?
43		How does the organization ensure integration of external documents into the product realization process or any other affected process?
	2-3.2 COMPETENCY MATRIX	
44		Have responsibilities and competences been defined for the preparation, approval, issue, and modification of quality documents?
	2-3.3 Access to Controlled Documents	
45	(a)	How is the documented information required by the quality program checked to ensure availability for use where and when it is needed?
46		how is the documented information required by the quality program adequately protected?
47	(b)	Has the organization prepared the following activities on documented information? - distribution, access, recovery, use - conservation and readability - management of change - availability
48		Have the persons responsible for the control and management of the documented information been defined in accordance with the competence matrix?
	2-4.1 General	
49		Does the organization have a documented procedure for the management, review, distribution, implementation of the TECHNICAL JOB FILE requirements for each internal Job/ PO?
	2-4.2 Preparation, Review and Approval of TECHNICAL JOB FILE.	
50	(a)	Have the following arguments been defined within the TECHNICAL JOB FILE. requirements? - customer PRODUCT requirements and technical specifications - logistical requirements - production feasibility - project planning - Verification activity - validation, monitoring, measurement, INSPECTION, and testing activities - acceptance criteria
51		How is the TECHNICAL JOB FILE checked to ensure availability for use where and when it is needed?
52		Have access procedures been defined for the personnel involved in the documentation according to their functions and responsibilities?
53	(b)	In the TECHNICAL JOB FILE. are defined the processes in which credential personnel is required?

54		Has the technical and quality personnel determined and documented the inspection and testing to be addressed in the TECHNICAL JOB FILE?
55	(c)	Is the TECHNICAL JOB FILE. reviewed by competent personnel who have access to the latest applicable documentation?
56		Are responsibilities for TECHNICAL JOB FILE. preparation, review, and approval identified based on competency?
57	(d)	Are organization responsibilities for the review and approval of the client's TECHNICAL JOB FILE. requirements identified based on competency?
	2-5.1 General	
58		Is there documented information that describes the activities/processes that have a qualitative impact on the PRODUCT as: - Procedures - Work instructions - Technical / functional drawing - Acceptance criteria - Sampling methods - Quality plans
59		Have acceptability criteria been defined for each activity / process in accordance with the requirements?
	2-5.2 Preparation, Review and Approving for Use	
60		Are responsibilities for the preparation, review and approval of documented information identified based on competency matrix?
	2-6.1 General	
61	(a)	Is there a documented procedure for the initial assessment, approval and use of qualified suppliers?
62		Does the organization established, implemented, and maintained a documented procedure for managing orders to approved suppliers?
63	(b)	Does the organization communicate the suppliers the following requirements through documented information? - processes or Products to be supplied. - criteria for the approval of methods, processes, and equipment - releases of PRODUCT and services - competence and credential of personnel - control and monitoring of supplier performance - verification or validation activities to be carried out at the supplier
	2-6.2 Preparation, Review and Approval for Release of Purchase Orders	
64	(a)	Does the organization communicate through documented information to suppliers the criteria for the acceptance of Products and services?
65	(b)	Is the purchase documentation checked, before issuing to the supplier, by competent personnel to confirm compliance with the requirements of the TECHNICAL JOB FILE? requirements?
66	(c)	Are responsibilities for the preparation, review and approval of purchase orders identified based on competency?
	2-7.1 General	
67		Has the organization restricted the PROCUREMENT of Products or processes in the following categories? - approved suppliers, suppliers indicated by the customer, customer.
68		Are the purchase from unapproved suppliers prevented by a properly control?

	2-7.2 Procurement of Product from an Approved Supplier	
69		Has the organization implemented a documented procedure for? - select the types and extent of controls. - acceptance criteria - identification of materials - handling of Products - storage of Products
	2-7.3 Procurement of Product from a Supplier Specified by The Customer	
70		if the customer requires a specific supplier for the supply of Products or processes, does the organization use the same methods identified in point 2-7.2?
	2-7.4 Customer Supplied Product	
71		in case the customer supplies Products or processes, does the organization use the same methods identified in point 2-7.2?
	2-7.5 Approved Supplier Evaluation	
72		Has the organization determined a documented procedure for evaluation, selection, performance monitoring and re-evaluation of suppliers, based on the ability to provide processes or Products and services in accordance with the requirements?
73	(a)	Presence of an ASME certificate in accordance with the requirements
74	(b)	Verification and acceptance of objective evidence of the quality of the Products and services provided, by competent and authorized personnel for the evaluation identified in competency matrix
75	(c)	Audit results carried out on supplier management system by appointed, competent and certified personnel.
76	(d)	Analysis of previous performances carried out by competent and AUTHORIZED PERSONNEL as: -INSPECTIONs at the supplier -surveillance at the supplier -quality of the Products supplied -time to delivery
	2-7.6 Source Documentation Package	
77		Is there evidence that all material certifications, process certifications and certifications of compliance are supplied with the materials are traceable? (i.e. batch number, heat codes.)
	2-7.7 Supplier Performance Management	
78		Has the organization included in his audit program schedule, audit process and audit PRODUCT at the supplier?
79		Has the organization determined, based on the risks, the performance of the supplier, the certifications obtained, and the organizational level, the criteria on the need, the type and frequency of audits?
80		Is the system, process or PRODUCT audit carried out at the supplier's premises performed by AUTHORIZED PERSONNEL of the organization?
81		Are the reports of these audits kept and maintained by the organization?
82	(a)	Are the personnel performing quality management system audits at the supplier premises (second type) identified in the competence matrix?
83		Has the organization determined, based on the risks, the performance of the supplier, the certifications obtained, and the organizational level, the criteria on the need, type, and frequency of audits?
84	(b)	Are the personnel performing a process INSPECTION or surveillance activity at the supplier premises identified in the competency matrix?
85	(c)	Are the personnel performing PRODUCT INSPECTIONs and /or TEST activity at the supplier premises identified in the COMPETENCY MATRIX?
	2-7.8 Receiving Inspection	
86		Have the responsibilities for the control of incoming material been defined in procedures and work instructions?
87		Have work instruction, extension methods, acceptability criteria been defined for the verification of Products received in the case of control by random sampling?
88		Is inspected material adequately identified as to acceptance or rejection and traceable to receiving INSPECTION report?

89		Do supplier corrective action requests requiring root cause investigation show responses are analyzed?
90		Does the organization have a documented procedure to ensure that the processes, Products and services purchased comply with the current legal requirements applicable in the country of receipt, in the country of dispatch and in the country of destination identified by the customer?
91		Does the organization keep documented information of these activities and all necessary actions resulting from the assessments?
92	(a)	Are the Products received by approved supplier or imposed supplier, for further use on the organization's products, verified with the acceptability criteria?
93	(b)	Are the PRODUCT received by the customer for further use on the organization's Products verified with the same acceptability criteria as the approved supplier?
	2-7.8 Receiving Inspection	
94		Are the quality personnel assigned to the control of incoming material and services defined in the competency matrix?
	2.8 Control and identification of products	
95		Has the organization planned, documented, and implemented control plans to verify compliance with the requirements, for each subsystem, component and / or production material and all externally sourced Products and services throughout the production processes?
96		Are appropriate work instructions available where needed that accurately describe all work methods including INSPECTIONs and TESTs to be done during production?
97		Are parts correctly identified throughout the entire processing route, including storage?
98		Is there a technique defined to check for unidentified material, containers, loose parts etc?
99		Is a batch traveller (or route card) utilized and does it clearly define all processing and INSPECTION steps for each PRODUCT lot as it progresses through manufacturing and TEST?
100		Do the records indicate the completed manufacturing processes with the names and dates of those who performed each identified step?
101		Does this card reflect the sequence of manufacture?
102		Are there procedures and practices to prevent contamination or degradation of parts from dust, oil, hazardous substances, or other environmental contaminants?
103	(a)	Is traceability of critical and significant characteristics assured?
104		Are record retention periods in accordance with client, standard and regulatory requirements implemented and followed?
105		Are raw material and parts identified to allow traceability to the subcontractor's process?
106		does the organization determine and implement the identification of non-conform or suspect Products?
107	(b)	Is the process for identification and handling of reworked material documented and followed?
	2-9.1 General	
108	(a)	Have the processes and activities that influence the quality of the PRODUCT been defined and have the competent personnel involved in these processes/activities been identified?
109		Have the processes on the competency matrix been defined?
110		For each process or activity that has an impact on the quality of the product or service, has the relevant personnel been defined in the competency matrix?
111		Are written improvement plans are implemented to reduce sources of variation?
112	(b)	Has the organization established, implemented, and actuated procedures or work instruction for the PRODUCT to use documents that identify the technical and quality requirements included TECHNICAL JOB FILE.?
113		Are these process documents also used for products destined for warehouse?

	2-9.2 Identifying and Controlling a SPECIAL PROCESS	
114		Has the organization identified the SPECIAL PROCESS?
115		Are credentials and responsibilities defined for personnel performing special processes?
116	(a)	Are the personnel carrying out SPECIAL PROCESS, formally trained and in possession of credentials according to the technical job file or customer requirements or competency matrix?
117		Are responsibilities and authorities defined for the verification of the results of special processes?
118	(b)	Is there a documented, up-to-date training/certification plan for personnel performing special processes?
119		Is the responsibility for executing / verifying these plans defined?
120	(c)	Is the competence of the personnel performing SPECIAL Processes defined, current and described in the competency matrix?
	2-9.3 Planned Maintenance	
121		Does the organization determine and implement a documented maintenance system?
122		Are the process equipment to make a PRODUCT that meets the requirements identified?
123		Is the preventive maintenance schedule is followed since PRODUCT cannot be made with tools that are outside of maintenance period?
124		Are tools stored in an appropriate, clearly defined area with systematic tracking that provides traceability, particularly of customer/owned tools and equipment?
125		Are periodic maintenance activities established, implemented, and documented?
126		Are the resources required for periodic maintenance established?
127		Are the personnel involved in periodic maintenance and repairs competent and identified and have the necessary skills?
128		if the periodic maintenance and repair service is outsourced, has the supplier been approved in accordance with what is specified in par 2-7.5?
129		Is the documentation relating to periodic maintenance and repairs kept and the responsibilities and storage period defined?
	2-10.1 General	
130		Have control and INSPECTION plans (or equivalent documents) been established, implemented, documented, and maintained to ensure compliance with present standard and technical job file requirements?
131		Control plans or INSPECTION instructions, compliant with update TECHNICAL JOB FILE requirements?
132		Is all required INSPECTION and TEST equipment available and adequate for the relevant standard of technical job file requirements?
133		Are all required INSPECTION TEST equipment and fixtures within the calibration system?
134		In the case of verification of PRODUCT s manufactured in batches, lots, heats have sampling methods been implemented, documented, and maintained for the control of conformity?
	2-10.2 Inspections	
135		Has the organization planned and implemented INSPECTIONs during each job phase to verify compliance with requirements, where applicable?
136		Has the organization defined, implemented, and documented through the technical personnel in charge the type, methods and extent of INSPECTIONs and defined the related characteristics to be inspected?
137		Are the responsibilities and authorities of the personnel who carry out, document, and evaluate the results of the INSPECTIONs defined?
	2-10.3 Tests	
138		Has the organization planned and implemented TESTs during each job phase to verify compliance with requirements, where applicable?
139		Has the organization defined, implemented, and documented through the technical personnel in charge the type, methods and extent of TEST s and defined the related characteristics to be tested?

140		Are the responsibilities and authorities of the personnel who carry out, document, and evaluate the results of the tests defined?
	2-10.4 Testing Laboratory	
141	(a)	Does the organization for TEST carried out externally, use laboratories on the list of approved suppliers?
142		Does the organization verified for ISO 17025 accredited laboratories that the accreditation scope is in accordance with the TEST s specification to be performed, not expired, withdrawn, or suspended?
143	(b)	For non-accredited laboratories, the quality manager carried out periodic audits to confirm the supplier's ability to comply with the criteria of ISO 17025?
144		Has the customer's approval been requested in the case of using a non-accredited laboratory?
	2-10.5 Inspection and Test Status Indicators	
145		Has the organization ensured that all records that provide evidence that the work has passed/ not pass specific acceptance criteria for INSPECTIONs and /or TESTs, are maintained, identified on the PRODUCT or traceable?
146	(a)	Has the organization established and implemented documented information to ensure immediate identification and removal from use of any equipment, PRODUCT, tooling, and machinery found to be non-compliant? As: -Has failed in operation in any parameter -Shows evidence of physical damage -Is suspect for any reason -Has not been calibrated in acc with the established time scale -etc.
147	(b)	Have methods been defined and implemented to identify the status of INSPECTIONs and TESTs on the PRODUCT, by using markings, authorized stamps, tags, labels, routing cards, INSPECTION records, physical location, barcode, quick response (QR), frequency identification (RFID) or other suitable means which indicate the conformance or nonconformance of work performed?
	2-10.6 Competency Requirements – Inspection and Test Personnel, Production and Quality Personnel	
148	(a)	Has the organization defined the responsibility and authority of the personnel assigned to controls during all stages of production, the final release of the PRODUCT and INSPECTIONs/TESTs?
149		Have these responsibilities and authorities of the personnel assigned to controls during all stages of production, the final release of the PRODUCT and INSPECTION/TEST been defined on the competency matrix?
150	(b)	Has the organization identified and established procedures for assessing personnel to INSPECTION and TEST activities (including instrumentation and equipment) based on their skills, experience, and knowledge?
151		Has the organization identified on the competency matrix the personnel assigned to the INSPECTION and TEST activities in possession of the credentials, considering the type of credentials and the organization that iussued the credentials?
152		Has the organization identified and established procedures for the maintenance and proficiency of personnel credentials?
153		Have the personnel with credentials assigned to non-destructive testing activity been listed in the competency matrix?
	2-11.1 General	
154		Are measuring devices and gauges and TEST equipment (included software) routinely calibrated and controlled per documented procedures?
155		Have the control periodicity and acceptability criteria been identified in the instrument management system?
156		Is the documentation relating to periodic calibration kept and the responsibilities and storage period defined?
157		Are appropriate controls in place to verify the suitability and accuracy of computer software prior to initial use in checking PRODUCT quality or control of processes?
158		Is there a formal method use to qualify new o rebuilt quality devices or TEST equipment prior to use?
	2-11.2 Calibration of Measuring and Testing Equipment	
159	(a)	Are gauges and TEST equipment calibrated against standards traceable to a recognized regulatory body or agency?
160	(b)	Has the person responsible for internal calibrations been appointed based on competence, knowledge, and experience (at least ISO 17025)?
161		Has the personnel who internally calibrates the instrumentation that affects the quality of the PRODUCT or process been identified and has the necessary competence and training?

	2-11.3 Calibration Laboratory	
162		Does the organization for calibration carried out externally, use laboratories on the list of approved suppliers?
163	(a)	Does the organization verified for ISO 17025 accredited laboratories that the accreditation scope is in accordance with the calibrations to be performed, not expired, withdrawn, or suspended?
164	(b)	For non-accredited laboratories, the quality manager carried out periodic audits to confirm the supplier's ability to comply with the criteria of ISO 17025?
165		Has the customer's approval been requested in the case of using a non-accredited laboratory?
	2-11.4 Calibration Status Indicators	
166		Is each item of INSPECTION, TEST, measuring equipment and fixtures correctly and uniquely identified (including next calibration date) within the calibration system?
167		Has his status been identified?
168		Is there evidence that in-process routine calibration of TEST rigs (and ancillary equipment) has been carried out to schedule?
169		Is these information present on the instrumentation?
170		Is the environment in which TEST are performed appropriate?
171		Is there evidence of proper handling of TEST equipment?
172		Are the correct gauges and INSPECTION devices, as detailed on TECHNICAL JOB FILE., available?
173		Is all measuring and TEST equipment in good working order?
	2-11.5 Discrepancies in Measuring and Testing Equipment	
174		Is assessment made to check the validity of previous measurements done on Products where out-of-calibration measuring devices were used? -the previous measurement results obtained with this device are verified and stored -the customer is notified in case of shipment of the Products -Products measured with this instrument are considered as non-conform -corrective actions are open
	2-12 Handling, Storage and Shipping	
175		Has the organization established specification for handling, storage, cleaning, packing, shipping, and preservation to ensure PRODUCT or equipment compliance? Are readily accessible?
176		Do these documentations clearly identify the responsibility?
177		Are these specifications reviewed on a regular basis?
178		Is proper equipment and methods used to prevent PRODUCT damage or loss in all phases of the material handling?
179		Are areas around the facility clean and orderly and are tools and equipment properly stored and readily for use and is lighting and air quality are adequate?
180		Are the packaging materials adequately protected against deterioration before use?
181		Is stored PRODUCT /material and equipment periodically inspected, and where applicable, actions are taken to prevent deterioration per documented procedures?
182		Does the organization consider the obsolete PRODUCT as a non-conformity PRODUCT?
	2-13.1 General	
183	(a)	Has the organization established a documented procedure and the responsibility for non-conformity PRODUCT or process results based on? - identification - Correction - Segregation, containment, return or suspension of the supply - Customer information - Obtaining the concession authorization
184	(b)	
	2-13.2 Nonconformity Status Indicators	
185		Has the personnel authorized to carry out the actions provided for in point 2-13.1 been identified?

	2-13.3 Dispositioning of Nonconformities	
186	(a)	Has the AUTHORIZED PERSONNEL promote, carry out, provide corrective actions?
187		Have responsibilities and authorities been defined in the management of corrective actions?
188	(b)	Has quality personnel established and implemented containment (immediate) actions and effective where necessary?
189		Is rework material, parts and assemblies are re- inspected or re-tested to confirm compliance to requirements?
190		Is PRODUCT traceability maintained to facilitate problem evaluation and corrective action?
191		Is the use of nonconforming material documented under a formal waiver or concession system?
192		Is there a recall system to notify customers of nonconforming PRODUCT that already been shipped?
193	(c)	Have escalation procedures been established in case of conflict for the resolution of non-conformities?
	2-13.4 Customer Complaints	
194		Is there an effective method used to manage products claimed and returned by customer such root cause analysis, corrective actions, preventive action, lesson learned?
	2-13.5 Competency Requirements - Dispositioning of Nonconformities	
195		Has competent personnel to evaluate customer complaints or non-conformity, been identified?
196		Are the personnel involved in the assessment of customer complaints or non-conformity, present in the competency matrix?
	2-14.1 General	
197		Does the organization have a documented procedure that ensures that outputs that do not comply with their requirements are identified and controlled to prevent their use or involuntary delivery?
198	(a)	Has the organization established documented actions to eliminate the causes of PRODUCT or process non-conformity? As -Reviewing and classification of non-conformities -Determining cause of nonconformities -Evaluation action to prevent recurrence -Determining or implementing action needed -Recording of results -Reviewing corrective action taken for effectiveness
199	(b)	in the case of significant non-conformities that require corrective actions, have responsibilities and implementation times been established?
200		Have criteria been established for reviewing the corrective actions and evaluating their effectiveness?
	2-15.1 General	
201		Has the organization established, implemented, and maintained a periodic monitoring by the process / department owners whose results are documented in the management review? Included: a) the safety culture b) the adequacy of the resources and environmental and safety conditions required to fulfill their duties and responsibilities, including those for the personnel they manage. c) performance of suppliers that are internal and external to the Certificate Holder. d) the nonconformities and corrective actions to determine the effectiveness of the corrective actions to prevent recurrences. e) the processes and the quality of work
	2-15.2 Internal Audits	
202		The organization has established, documented, implemented, and maintained an audit program that includes the frequency, methods, responsibilities, planning requirements and reporting as a function of production processes, changes affecting the organization and the results of previous audits?
203		has the organization conducted internal audits at scheduled intervals to provide information on the quality management system so that? -the system complies with the requirements of the quality management system -the system complies with the requirements of QSP -it is effectively implemented and maintained

	2-15.3 Competency Requirements –Internal Auditors and Auditors	
204	(a)	Are the personnel carrying out internal Audit formally trained and competent?
205		Are personnel in charge of internal audits certified as lead auditors or do they perform their duties under the direction of a certified lead auditor?
206		Does EXECUTIVE MANAGEMENT guarantee and monitor compliance with the impartiality of the audit /audit process, in accordance with the policy and the responsibilities of each function?
207	(b)	Are the personnel carrying out second type Audit formally trained and competent?
208		Have the minimum competence requirements for the personnel assigned to carry out internal and second part audits been defined and respected?
209	(c)	Are audit assignments made based on defined requirements and the competency matrix?
	2-15.4 Procurement of Auditing Services	
210		if the auditing service is carried out by an external supplier, does the organization use approved suppliers?
211		Does the supplier's personnel responsible for carrying out the audits meet the requirements as set out in point 2-5.3?
	2-15.5 Executive Management Review of the Quality Program	
212	(a)	Does the organization review the quality management system at planned intervals to ensure its continued suitability, adequacy, effectiveness, and alignment with the management's strategic direction?
213		Has responsibility been established for preparing the EXECUTIVE MANAGEMENT review containing at least the following information? 1) results of the monitoring activities performed by department managers. 2) feedback from customer surveys or input from sales personnel 3) audit reports of suppliers 4) internal audit reports of the quality program 5) trending analysis of nonconformities and corrective actions 6) a review current resource levels
214	(b)	in the execute management review outputs, have all the previous points been addressed and described?
215		In the conclusions of the EXECUTIVE MANAGEMENT review, have the following aspects been addressed and evaluated?
216	(1)	existence of a healthy company culture for quality and safety
217	(2)	existence of a knowledgeable and competent workforce
218	(3)	suitability, adequacy, and effectiveness of its quality program to correctly process a CUSTOMER AGREEMENT or PRODUCT specification into realization of a conforming PRODUCT
219	(4)	suitability of current resource levels or need for recruitment or additional training of existing personnel
	2-16.1 General	
220	(a)	Has the organization defined and documented a record retention policy?
221		Does the organization have a documented process that describes the distribution, implementation of all customer standards / specifications, technical job file and related reviews?
222	(b)	Does the organization identify, store, protect, retain, retrieve, and dispose of records?
	2-16.2 Documents Retained as a Record	
223	(a)	Has the organization implemented a traceability procedure for the relevant documentation relating to the product and its conservation?
224	(b)	Has the organization implemented a procedure for management the relevant documentation relating to the quality system and its conservation?
	2-16.3 Record Retention	
225		Has the organization defined a retention period for control and inspection documents in accordance with the quality system, customer contracts, product specifications or the laws in force?

	2-17.1 General	
226		Does the certificate of conformity accompanying the finished PRODUCT, made in accordance with the quality program certified by ASME, identify the quality *Program Supplier Certificate* number, his expiry date and the edition, revision and issue date of the organization Quality Manual or equivalent Quality Document?
	2-17.2 Use of ASME Certificate to Identify Products	
227	(a)	Does the Quality Manual or equivalent Quality Document contain a declaration that the certificate of conformity described in the previous point that accompanies the PRODUCT confirm that all PRODUCT has been made in according to all the requirements of the QPS standard and the technical job file generated from original source document?
	2-17.2 Use of ASME Certificate to Identify Products	
228	(b)	Does the Quality Manual or equivalent Quality Document contain a declaration of responsibility that the PRODUCT manufactured comply with all the requirements of the QPS standard implemented in its quality system certified by ASME?
229	(c)	Has the certificate of conformity been signed by the quality manager?
230		Have PRODUCT conformity checks been carried out and documented before release to confirm compliance with the requirements of the technical job file and the requirements of the quality program suppler certificate?
231		Have the functions that are authorized to sign the certificate been identified in the absence of the quality manager?
232	(d)	Have the responsibilities and methodologies for communicating changes of quality manager of the certified organization to ASME been defined?